

Application Serial No. 09/901,014  
Amendment dated 8 September 2006  
Reply to Office Action mailed 8 March 2006

*REMARKS*

Claim 70 has been amended to more clearly claim the present invention. Thus, the individual elements and their relationships have been set forth in the claim. For example, the elements of a reaction chamber and a solution, which were previously referenced in the claim and are shown in Figure 2, have specifically been added to the language of the claim. The solution is specified as one for fixing or processing a tissue sample, as supported, for example, in Examples 1, 6 and 7. The tissue sample and the ultrasound transducer have been indicated to be immersed in the solution as supported by Figure 2. The ultrasound transducer and ultrasound generator have been separately set forth. In view of claim 73 referring to a second sensor, the sensor in claim 70 has been specified as a first sensor. Finally, claim 70 has been amended to specify that "the system causes the tissue sample to become fixed with no or minimal damage to the tissue sample." Support for tissue fixation can be found at, for example, page 10, lines 29-30 and page 21, lines 25-29. Support for no or minimal damage to the tissue sample can be found at, for example, page 12, lines 1-3. The specification describes what is meant by no or minimal damage to the tissue, such as retaining excellent morphology and good preservation of protein and RNA. See for example, page 12, lines 17-18, page 18, lines 28-29, page 20, lines 28-31, page 21, lines 25-29 and page 23, lines 9-12.

Claims 72, 74 and 75 have been amended to be consistent with the amendments made to claim 70.

Claim 73 has been amended to more clearly claim the additional feature of the system.

Claim 76 has been canceled by the present amendment, because the language of the claim already appears in claim 70.

Claims 92-95 have been amended to be consistent with the amendments made to claim 70.

Claim 96 has been amended to more clearly claim the additional features of the system.

Claim 97 has been canceled.

New claims 98-104 have been added. Claim 98 is a combination of amended claim 70 and claims 77 and 79. Claim 99 corresponds to claim 78. Claim 100 corresponds to amended claim 72.

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Claim 101 corresponds to amended claim 73. Claim 102 corresponds to amended claim 74. Claim 103 corresponds to amended claim 75. Claim 104 corresponds to amended claim 96.

It is submitted that these amendments do not constitute new matter, and their entry is requested.

The Examiner rejected claims 70, 72-79 and 92-97 under 35 U.S.C. § 112, second paragraph for being indefinite. Although Applicant submits that a “tissue sample” is definite to a skilled artisan and does not mean a tissue sample in a body, claim 70 has been amended to specify that the tissue sample is immersed in the solution which is in the reaction chamber. This language makes it clear that the tissue sample is not in the body.

In view of the above amendments and remarks, it is submitted that the claimed invention is definite to a skilled artisan. Withdrawal of this rejection is requested.

The Examiner rejected claims 70, 72-79, 96 and 97 under 35 U.S.C. § 102(b) as being anticipated by Northrup et al. (US 5,639,423). Applicant submits that Northrup et al. does not anticipate the claimed subject matter because it does not disclose all of the elements as set forth in the amended claims.

Specifically, Northrup et al. discloses an integrated microfabricated instrument for manipulation, reaction and detection of microliter to picoliter samples. The small size of the reaction chambers of the Northrup et al. device are said to facilitate rapid thermal cycling. Northrup et al. further discloses that ultrasonic Lamb-wave devices may be used as sensors, pumps and agitators. See, for example, col. 4, lines 49-65, col. 7, lines 29-31, col. 7, lines 35-41, col. 7, lines 61-62 and col. 8, lines 20-23. The use of a Lamb-wave device as a mixer for a reaction chamber is described at col. 11, lines 31-38. This latter description details how the Lamb-wave mixer noted at col. 7, lines 29-34 operates to mix the reactants in the reaction chamber. It is clear that this reference to a Lamb-wave device in Northrup et al. mixes the reactants in a reaction chamber and does not fix a tissue sample.

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In addition, Northrup et al. discloses that ultrasonic waves are useful for disrupting and exposing cell components through lysis. See, col. 5, lines 44-47. Northrup et al. teaches that this utilization of ultrasonic waves is to “disrupt and expose cell components through lysis, and to unravel large or long chain molecules such as DNA and proteins via disruption of secondary structure.” Northrup et al. specifically teaches extraction of DNA from fixed cells using macroscale sonication (see, col. 5, lines 52-57) as well as sonication extraction of DNA from intact cells, microorganisms, tissues and other analytical samples (see, col. 5, lines 57-61). The extracted DNA is then used for subsequent techniques, such as PCR. It is clear from these passages that Northrup et al. teaches the use of ultrasound to extract DNA from a variety of samples which leads to the destruction of the samples. Thus, the system of Northrup et al. does not fix a tissue sample with no or minimal damage to the tissue sample as specified in the claims.

The Examiner contends that the device of Northrup et al. can be used to process fixed cells as well as tissue samples. However, the processing described in Northrup et al. is disruptive and not preservative as required by the claimed subject matter. Moreover, the instant application seeks to preserve the morphology of samples for subsequent processes that provides information about proteins and nucleic acids, as well as the histological appearance of the tissue sample. Indeed, the subsequent techniques proposed by Northrop at col. 6, lines 1-10 do not involve any quality of the sample other than the extracted DNA.

Northrup et al. does not disclose or even suggest a system in which ultrasound is used to process or fix tissue samples such that they retain their normal histology or pathology, nor does it suggest a system in which an ultrasound transducer and a tissue sample are immersed in a solution in a reaction chamber in which the solution is a solution for fixing or processing a tissue sample. Because Northrup et al. does not disclose each element of the system of the claims, the reference does not anticipate the claims of the present application.

In view of the above amendments and remarks, it is submitted that the claimed invention is not anticipated by the cited prior art. Withdrawal of this rejection is requested.

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The Examiner rejected claims 92-95 under 35 U.S.C. § 103(a) as being obvious over Northrup et al. in view of Chu (US 5,958,341). Chu was cited by the Examiner to show use of the claimed solutions for tissue fixation. It is submitted that the Examiner is in error in this rejection.

Specifically, as detailed above, Northrup et al. does not describe all of the elements of the claimed invention. Chu does not cure the deficiencies of Northrup et al. Thus, Applicant submits that the combination of Chu with Northrup et al. does not render the claimed subject matter obvious.

In view of the above amendments and remarks, it is submitted that the claimed invention is not obvious from the cited references. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, Applicant believes that the present claims satisfy the provisions of the patent statutes and are patentable over the cited prior art. Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned to expedite the prosecution of the application..

Respectfully submitted,

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